

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### Release of Establishment Inspection Report to the Inspected Establishment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it is revising its policy regarding the release of the Establishment Inspection Report (EIR) to inspected establishments. Effective April 1, 1997, a copy of the narrative portion of the EIR will be routinely provided to the inspected establishment once the agency determines that the inspection is "closed" as set forth in the regulations.

**FOR FURTHER INFORMATION CONTACT:** Charles I. Ahn, Office of Regulatory Affairs (HFC-132), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5637.

**SUPPLEMENTARY INFORMATION:** Under the Freedom of Information Act (FOIA) and FDA's regulations governing disclosures as set out in part 20 (21 CFR part 20), inspectional information, including the list of inspectional observations (FDA-483), EIR, and the agency's communication with the regulated establishment, must be disclosed upon request by any member of the public unless exempt. When requested according to established FOI procedures, the agency has made the inspection-related information available to requestors in accordance with the above statutory and regulatory requirements. That is, the information becomes releasable once the inspection is deemed closed by the agency. Establishments wishing to obtain a copy of FDA's inspection report of their own establishment have been required to follow the same procedure. A number of industry associations have expressed concern that copies of EIR's may be released to other requestors before the inspected establishments receive the copies they requested. Consequently,

these groups have approached the agency to request that it provide a copy of the EIR following an inspection of their facilities.

The agency has considered this request and determined that a copy of the narrative portion of the EIR should be routinely provided to the inspected establishment once the agency concludes that the inspection is closed. For the purpose of this directive, the term "closed" will have the same meaning as it has under § 20.64(d)(3).

Dated: April 7, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4200-N-51]

### Notice of Proposed Information Collection for Public Comment

**AGENCY:** Government National Mortgage Association, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments due: June 13, 1997.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Sonya K. Suarez, Government National Mortgage Association, Office of Policy, Program and Risk Management, Department of Housing & Urban Development, 451 7th Street SW., Room 6226, Washington, DC 20410.

**FOR FURTHER INFORMATION CONTACT:** Sonya K. Suarez, on (202) 708-2272 (this is not a toll-free number) for copies

of the proposed forms and other available documents.

**SUPPLEMENTARY INFORMATION:** The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

*Title of Proposal:* Issuer's Monthly Accounting Reports.

*OMB Control Number:* 2503-0004.

*Description of the need for the information and proposed use:* Issuers use these forms to report monthly on their securities accounting. Information is necessary to assure issuers are performing pursuant to the terms of the guaranty agreement and investors are receiving all funds due them.

*Agency form numbers:* HUD 11710A, 1710B, 1710C, 1710D and 1710E.

*Members of affected public:* Business or other for-profit and the Federal Government.

*Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:*

*Reporting Burden:*

Form 11710	Total respondents	Responses per respondents	Total responses	Hours response	Total hours
A .....	620	656	406,437	*.012	4,877
B .....	10	12	120	.25	30
C .....	2	2	4	.16	.6
D .....	620	12	7,440	.25	1,860
E .....	620	24	14,880	.16	2,381
		706	428,881		9,149

\*14.4 min. per response/60 min. per hour=.24 hrs. × .05=.012.